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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,237	07/17/2003	Peter Robert Baum	2873-USA	4633

22932 7590 08/08/2006

IMMUNEX CORPORATION
LAW DEPARTMENT
1201 AMGEN COURT WEST
SEATTLE, WA 98119

EXAMINER

HADDAD, MAHER M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/622,237	Applicant(s) BAUM ET AL.	
	Examiner Maher M. Haddad	Art Unit 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 April 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 14 April 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: None.
 Claim(s) objected to: None.
 Claim(s) rejected: 18 and 20-23.
 Claim(s) withdrawn from consideration: None.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
 13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: 1. Claims 18 and 20-23 stand rejected under 35 U.S.C. 102(e2) as being anticipated by U.S. Patent No. 6,642,360, as is evidenced by Bost et al for the same reasons set forth in the previous Office Actions mailed 7/28/04 and 7/15/05.

Further, the '360 patent teaches a composition of matter comprising an anti-PRO355 antibody (see col. 19 lines 24-30 in particular).

2. Claims 18 and 20-23 stand rejected under 35 U.S.C. 102(e1) as being anticipated by Pub. No. U.S. 2002/0198147 A1, as is evidenced by Bost et al for the same reasons set forth in the previous Office Actions mailed 7/28/04 and 7/15/05.

Further, the '360 patent teaches a composition of matter comprising an anti-PRO355 antibody (see paragraph 140 in particular).

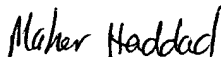
Applicant argues that the basis for rejecting the declaration runs counter to legal precedent and cites Noelle v. Lederman court decision. "Therefore, based on our past precedent, as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in public depository, the applicant can then claim an antibody by its binding affinity to that described antigen." 60 USPQ2d 1541, 1508 (CAFC 2004). Applicant submits that there is no dispute that Applicants discovered and fully disclosed the fully characterized antigen of SEQ ID NO:2/ prior to the '360 patent and the '147 publication. Applicants conclude that they are entitled to claims covering antibodies to that antigen. Applicant further submits that the 1.131 declaration show Applicants were in possession of a fully characterized antigen.

Applicant is reminded that in Noelle v. Lederman, both parties were claiming antibodies. Lederman claimed antibodies to the human protein, while Noelle claims antibodies to the mouse and human proteins as well as the protein generically. The Court held "Patent claim directed to any antibody which is capable of binding to particular antigen has sufficient support in written description that discloses "fully characterized" antigens; thus, if applicant has disclosed fully characterized antigen, either by structure, formula, chemical name, or physical properties, or by depositing protein in public depository, then applicant can claim antibody by its binding affinity to that described antigen." The Court found that Noelle's generic claims and the claims to the human protein did not descriptive support in the original disclosure under 35 USC 112, first paragraph, written description.

Here, in the instant application, applicant is relying upon prior conception and reduction of practice of the protein (SEQ ID NO: 2) only to provide written description for antibodies to that protein. Applicant's prior conception and reduction does not provide written support for the current claims drawn to antibodies in the absence of sufficient written description or evidentiary support for antibodies.

Applicant possession of a fully characterized antigen of SEQ ID NO: 2 cannot be extrapolated to claims to an antibody to the antigen. Applicant's Declaration has not shown as much as the prior art of the '360 patent and the '147 publication. Therefore, Drs. Peter Robert Baum and William Christian Fanslow III declaration to establish that applicants were in possession of SEQ ID NOs 2 and 4 prior to december 3, 1997, which is prior to the earliest effective filing date for either of the cited is insufficient to overcome 102 rejections above because Applicant possession of a fully characterized antigen of SEQ ID NO: 2 cannot be extrapolated to claims to an antibody to the antigen. Also, it is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). Applicant's Declaration is directed to the amino acid sequence of SEQ ID NO:2, however, the claims are directed to antibodies to SEQ ID NO:2. It is unclear from the declaration when the claimed antibodies were made.

August 6, 2006



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